

REMARKS

Applicants' Representative thanks Examiner R. Cook for the helpful and courteous discussion of December 13, 2001.

Claims 5, 6, and 8 are pending.

I. The Rejection Of Claims 5-6 And 8 Under 35 U.S.C. § 112, 1st Paragraph

Claims 5-6, and 8 stand rejected under § 112, first paragraph, as non-enabled by the specification. The Office asserts that the specification is only enabled for compounds having affinity for FKBP-type immunophilins and requests that Applicants a limitation to that effect to claims 5-6, and 8 (Office Action, page 2, 3rd paragraph).

Applicants respectfully traverse with respect to claims 5-6 because these claims already contain the limitation "said compound has an affinity for FKBP-type immunophilins" (see Preliminary Amendment dated February 16, 2001, page 5, lines 5-6, and page 7, line 15).

Applicants respectfully traverse with respect to claim 8, which does not contain such a limitation.

According to the Federal Circuit, the test for enablement is whether the experimentation needed to make or use the invention is undue. *See In re Wands*, 858 F.2d 731, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). In rejecting claims for lack of enablement, the Examiner must first establish a *prima facie* case of non-enablement by providing reasons for doubting the disclosure's teaching of how to use the invention. *See In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995) (reversing a lack of

utility/enablement rejection for failure to adequately challenge a “presumptively correct assertion of utility in the disclosure”) and *In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971).

The Office has not provided any basis for concluding that it would require undue experimentation to make or use the present invention. The Office therefore has not satisfied its burden of making out a *prima facie* case of non-enablement. The present invention as claimed in claim 8 is a pharmaceutical composition as defined therein. The summary of the invention at page 4 describes compounds included in the compositions by one of their properties—an affinity for FKBP-type immunophilins. The Office has not shown how this property of these compounds relates to the level of experimentation required to make and use the compositions. In short, the Office has not shown how enablement is dependent on whether or not the property is recited in claim 8. Consequently, Applicants submit that the rejection for non-enablement should be withdrawn.

II. The Rejection Of Claims 5-6 and 8 Under 35 U.S.C. § 112, 2nd Paragraph
Claims 5-6 and 8 stand rejected as indefinite under the second paragraph of § 112.

The Office asserts that there is no antecedent basis in claim 11 for the term “a second hair revitalizing agent” (Office Action, page 2, 5th paragraph).

Applicants respectfully traverse. The term “a second hair revitalizing agent” imparts no indefiniteness to the claims. The specification refers repeatedly to the compounds of the invention as “hair revitalizing agents” (see, e.g., page 3, lines 20-23, and page 9, lines 10-13) and discloses that “the compounds can be administered with other hair revitalizing agents”

(page 26, lines 5-6). A person of skill in the art would thus recognize that by implication the compound of element (i) is the “first” hair revitalizing agent. Applicants draw the Office’s attention to U.S. Patent No. 6,239,164, which issued from parent U.S. Patent Application No. 09/369,860, and in which claims 21-24 contain the identical language. The Federal Circuit has reprimanded the USPTO for not recognizing its own precedent in rejecting claims under 35 U.S.C. § 112. In re Cortright, 49 U.S.P.Q.2d 1464, 1467 (Fed. Cir. 1999). The Office recognized, in allowing the parent case, that the term “a second hair revitalizing agent” would present no ambiguity to a person of skill in the art, and should follow that precedent in the present application. Applicants therefore request that the Office withdraw this rejection.

III. The Rejection Under 35 U.S.C. § 103(a)

Applicants thank the Office for withdrawing the rejection under 35 U.S.C. § 103(a), as indicated in the Interview Summary for the interview of December 13, 2001.

IV. The Provisional Rejections For Non-Statutory Double Patenting

Claims 5-6 stand provisionally rejected for non-statutory double patenting over claim 11 of co-pending U.S. Patent Application No. 09/781,427 (“the ‘427 application”) (Office Action, paragraph bridging pages 3-4).

Applicants submit that there is no overlap between claims 5-6 of the present application and claim 11 of the ‘427 application. Claims 5-6 contain the limitation that J and K, when joined to form a ring, form a 7 membered ring. See Preliminary Amendment dated February 16, 2001, page 5 (line 2), page 7 (line 13), and page 8 (line 8). In contrast, claim

11 of the '427 application is drawn to a 6 membered ring (see line 3 of claim 11 in the Preliminary Amendment filed February 13, 2001, in the '427 application). There is therefore no overlap in the claims. Applicants submit that this rejection is unfounded and should be withdrawn.

Claims 5-6 and 8 stand provisionally rejected for non-statutory double patenting over claims 17-32 of co-pending U.S. Patent Application No. 09/879,888 ("the '888 application") (Office Action, page 4, lines 1-3). Applicants request that this ground of rejection be held in abeyance pending indication of allowable material.

V. The Request For Identification Of Related Cases

The Office requested that Applicants identify related cases (Office Action, page 4, 3rd and 4th paragraphs). Applicants have filed concurrently herewith an Information Disclosure Statement listing related pending applications and issued patents. The items listed on page 1 of the attached Forms PTO-1449 have been submitted with the concurrently-filed Reply in U.S. Patent Application No. 09/825,896.

VI. References Cited But Not Received By The Office

The Office noted that certain references cited in a previously-filed Information Disclosure Statement were not considered by the Office because the references were not received (Office Action, page 4, last paragraph). Applicants have listed the references on a separate Form 1449 for the Examiner's convenience, and have submitted those missing references with the concurrently-filed Reply in U.S. Patent Application No. 09/825,896.

VII. CONCLUSION

Applicants submit that the pending claims are now in condition for allowance. If the Office has questions, the Office is invited to call Applicants' Representative directly at (202) 974-6018.

Please charge or credit Deposit Account No. 12-2475 for all fees as needed.

Respectfully submitted,

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